

APR 25 1997



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Washington, D.C. 20231

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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,338,325

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,338,325, which claims the human drug product FLOLAN® (epoprostenol sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Applicant is required to elect a single patent to be extended under 35 U.S.C. § 156 within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to these time periods.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 5, 1996 (61 Fed. Reg. 15,265). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (5,357 - 1,101) + 570 \\ &= 2,698 \text{ days (7.4 years)}\end{aligned}$$

Since the regulatory review period began July 1, 1979, before the patent issued (July 6, 1982), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 1, 1979 to July 6, 1982 is 1,101 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period:  $5,357 - 1,101 = 4,256$  days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued before the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed two years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for two years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

It is noted that applicant, Glaxo Wellcome Inc, has also filed an application for patent term extension of U.S. Patent No. 4,883,812 based upon the regulatory review of the product FLOLAN®. No more than one patent may be extended for a regulatory review period of a single product. 35 U.S.C. 156(c)(4). Normally, when applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. However, applicant has stated, in the application for patent term extension of U.S. Patent No. 4,883,812, that U.S. Patent No. 4,883,812 is elected, unless found ineligible for patent term extension. Accordingly, in the absence of a contrary election by applicant within ONE MONTH of the date of this notice, the above-identified application for patent term extension will be dismissed. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

If a contrary election is filed and issuance of the certificate of extension for the above-identified patent occurs, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,338,325
Granted:	July 6, 1982
Original Expiration Date:	July 6, 1999
Applicant:	Roy A. Johnson et al.
Owner of Record:	The Upjohn Company
Title:	PGI <sub>2</sub> Pharmacologically Acceptable Salts
Classification:	514/469
Product Trade Name:	FLOLAN®
Term Extended:	Two years
Expiration Date of Extension:	July 6, 2001

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.



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Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
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RE: FLOLAN®  
FDA Docket No.: 95E-0418